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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,036	01/20/2004	William L. Dunbar JR.	DEP 5033NP	1189
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/761,036	Applicant(s) DUNBAR ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6,21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,11-13 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 3,4,8-10 and 14-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/20/2004,08/16/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

It is noted that the subcombination/combination objection to claim 1 has been withdrawn. Upon further consideration, the phrase "adapted to couple said body and said inserter shaft, wherein said inserter shaft forces a spinal rod into the rod-receiving portion of said implant" is deemed to be solely a functional recitation. Therefore, claim 1 is considered to be drawn to the "subcombination", a tool.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 11, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (U.S. Patent No. 5,649,931).

Bryant et al. disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal end portion and a distal end portion. The distal end includes a first and second flexible branch (ref. #30). An inserter shaft (ref. #16) is slidably received within the body, the inserter shaft having a distal end. The tool also comprises a threaded collar (ref. #18), capable of coupling the body and the inserter shaft. The

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inserter shaft is capable of forcing a spinal rod into the rod-receiving portion of the implant. The body further comprises external threads capable of engaging with the threaded collar (ref. #36). A guide mechanism (ref. #20) is capable of co-operating with the shaft and the body whereby the guide mechanism limits the independent movement of the shaft within the body. Bryant et al further disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal and distal end portion, wherein an interior channel extending between the distal and proximal ends, the distal end portion having flexible branches and the proximal end portion having external threads (ref. #36). An inserter shaft (ref. #16), capable of being slidable within the interior channel of the body, has a proximal end portion, a distal end portion, and a transition zone located between the distal and proximal end portions, the transition zone having a diameter larger than the proximal end portions, and a collar having an internally threaded hollow body (ref. #38) and a central shaft attached to the hollow body (see unthreaded portion of collar ref. #18), wherein the central shaft limits the amount of independent motion between the inserter shaft and the collar. The independent movement limited is the rotational orientation and axial translation of the inserter shaft with respect to the body.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (U.S. Patent No. 5,649,931).

Bryant et al. disclose a tool (see FIGS. 4 and 5, ref. #10) comprising a body (ref. #14) having a proximal end portion and a distal end portion. The distal end includes a first and second flexible branch (ref. #30). An inserter shaft (ref. #16) is slidably received within the body, the inserter shaft having a distal end. The tool also comprises

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a threaded collar (ref. #18), capable of coupling the body and the inserter shaft. The inserter shaft is capable of forcing a spinal rod into the rod-receiving portion of the implant. The tool further comprises an outer sleeve rotatably and slidably mounted onto the distal end of the body, the sleeve being capable of being movable between a first and second position (ref. #18).

Claims 11-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (U.S. Patent No. 2,248,054).

Becker discloses a tool (see FIGS. 1-5) comprising a body (ref. #5) having a proximal and distal end portion, the distal end portion having branches. An interior channel extends between the distal and proximal end portions. An inserter shaft (ref. #12), capable of being slidable within the interior channel of the body, has a proximal end portion and a distal end portion. A guide mechanism is capable of co-operating with the shaft and the body whereby the guide mechanism limits the independent movement of the shaft within the body. The guide mechanism comprises a channel (ref. #10) and a pin (ref. #11) capable of fitting within the channel. The channel is located on the body and the pin is capable of fitting within the channel is located on the shaft. The pin and channel prevent the shaft from being removed from the body.

Allowable Subject Matter

Claims 3, 4, 8-10, and 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

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limitations of the base claim and any intervening claims, and rewritten to overcome the claims objections due to minor informalities set forth in this office action.

Response to Arguments

Applicant's arguments, see page 12, first and second paragraphs, filed 08/16/2006, with respect to the rejection of claims 11-14 under 35 U.S.C. 102(b) as being anticipated by Torode et al. (U.S. Patent Publication 2003/0004519 A1) have been fully considered and are persuasive. The rejection of claim 11-14 as being anticipated by Torode et al. has been withdrawn.

Applicant's other arguments [Bryant et al. (U.S. Patent No. 5,649,931) and Becker (U.S. Patent No. 2,248,054)] filed 08/16/2006 have been fully considered but they are not persuasive.

Applicant argues that the Bryant et al. (U.S. Patent No. 5,649,931) and Becker (U.S. Patent No. 2,248,054) references are not adapted to hold a closure mechanism for a spinal implant. In response to applicant's argument that the Bryant et al. and Becker reference have a different intended use and are not "adapted to hold a closure mechanism for a spinal implant", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.

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Ex parte Masham, 2 USPQ2d 1647 (1987). Currently, the statements of intended use and other functional statements do not impose any structural limitations on the claims distinguishable over the Bryant et al. and Becker references, which are capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). The examiner maintains that devices of Bryant et al. and Becker are capable of holding a closure mechanism of a spinal implant.

The 102 rejections under Bryant et al. (U.S. Patent No. 5,649,931) and Becker (U.S. Patent No. 2,248,054) are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER